

[0052]

CLAIMS

We claim:

1. A composition comprising mussel hydrolysate from Indian green mussel and at least one additive
2. The composition of claim 1, wherein the additive(s) is selected from the group consisting of carbohydrates, sugar, proteins, fats, water, and a pharmaceutically acceptable carrier.
3. The composition of claim 1, wherein at least one additive is a pharmaceutically acceptable excipient.
4. The composition of claim 1, wherein at least one additive is a pharmaceutically acceptable diluent.
5. The composition of claim 1, wherein the Indian green mussel is *Perna viridis*.
6. The composition of claim 1, wherein the concentration of mussel hydrolysate is between about 10 µg/mL and about 100 µg/mL.
7. The composition of claim 1, wherein the concentration of mussel hydrolysate is greater than about 100 µg/mL.
8. An extract of Indian green mussel comprising mussel hydrolysate.

9. A method of inhibiting osteoclast formation comprising contacting bone marrow cells with a composition comprising ~~an~~ <sup>product of</sup> mussel hydrolysate from Indian green mussel and at least one additive.
10. The method of claim 9, wherein the additive(s) is selected from the group consisting of carbohydrates, sugar, proteins, fats, water, and pharmaceutically acceptable carrier.
11. The method of claim 9, wherein at least one additive is a pharmaceutically acceptable excipient.
12. The method of claim 9, wherein at least one additive is a pharmaceutically acceptable diluent.
13. The method of claim 9, wherein the Indian green mussel is *Perna viridis*.
14. The method of claim 9, wherein inhibition of mononuclear TRAP-positive osteoclast formation is at least about 20%.
15. The method of claim 14, wherein inhibition of mononuclear TRAP-positive osteoclast formation is at least about 50%.
16. The method of claim 9, wherein inhibition of multinuclear TRAP-positive osteoclast formation is at least about 20%.
17. The method of claim 16, wherein inhibition of multinuclear TRAP-positive osteoclast formation is at least about 50%.

18. The method of claim 9, wherein inhibition of osteoclast formation is measured as inhibition of formation of osteoclasts from murine hemopoietic cells.
19. The method of claim 9, wherein the concentration of mussel hydrolysate is between about 10  $\mu\text{g/mL}$  and about 100  $\mu\text{g/mL}$ .
20. The method of claim 9, wherein the concentration of mussel hydrolysate is greater than about 100  $\mu\text{g/mL}$ .
21. A method of inhibiting bone resorption comprising contacting bone marrow cells with a composition comprising a mussel hydrolysate from Indian green mussel and at least one additive.
22. The method of claim 21, wherein the additive is selected from the group consisting of carbohydrates, sugar, proteins, fats, water, and pharmaceutically accepted carrier.
23. The method of claim 21, wherein the additive is a pharmaceutically acceptable excipient.
24. The method of claim 21, wherein the additive is a pharmaceutically acceptable diluent.
25. The method of claim 21, wherein the Indian green mussel is *Perma viridis*.
26. The method of claim 21, wherein the concentration of mussel hydrolysate is between about 10  $\mu\text{g/mL}$  and about 100  $\mu\text{g/mL}$ .
27. The method of claim 21, wherein the concentration of mussel hydrolysate is greater than about 100  $\mu\text{g/mL}$ .

28. The method of claim 21, wherein inhibition is measured as inhibition of RANKL-induced bone resorption.
29. The method of claim 28, wherein inhibition of RANKL-induced bone resorption is at least about 40%.
30. The method of claim 29, wherein inhibition of RANKL-induced bone resorption is at least about 70%.
31. A process for extracting mussel hydrolysate comprising:
- obtaining meat and mantle fluid of Indian green mussel;
  - fermenting meat and mantle fluid with protosubtiline (6% of the weight of meat) and 6% distilled water at a constant temperature of 40° C for two hours thereby forming a thick paste;
  - digesting the thick paste (12% of the total meat weight) with concentrated hydrochloric acid for 15 hours at 100° C  $\pm$  2° C;
  - cooling the resulting solution to room temperature and maintaining the pH by adding sodium hydroxide;
  - incubating the resulting solution in a separating flask for at least two days; and
  - removing the active extract-containing middle part of the solution.
32. A process for extracting mussel hydrolysate comprising:
- obtaining meat and mantle fluid of Indian green mussel;

fermenting meat and mantle fluid with a proteolytic enzyme at a constant temperature  
thereby forming a thick paste;  
contacting the paste with an acid;  
adjusting the resulting solution to room temperature and adding a base to maintain pH;  
incubating the resulting solution in a separating flask; and  
removing the active extract-containing middle part of the solution.

**33.** A process for extracting mussel hydrolysate comprising:

obtaining meat along with the mantle fluid of Indian Green Mussel;  
fermenting meat with mantle fluid with enzyme protosubtiline;  
fermenting 6% of the weight of meat with 6% distilled water at a constant temperature;  
digesting the thick paste with concentrated hydrochloric acid;  
digesting 12% of the total meat weight for 15 hours at  $100^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ;  
cooling the resulting solution at room temperature and maintaining the maintaining pH of  
the solution by adding sodium hydroxide;  
isolating the active extract by keeping the resulting solution in a separating flask for a  
few days and removing the middle part of the solution;

34. The process of claim 35, wherein the fermenting meat with distilled water is at a constant temperature of  $40^{\circ}\text{C}$  for about two hours.

35. The process of claim 35, wherein isolation of active extract is done in separating flask for 10 days prior to removal.